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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,182	07/11/2001	Albert C. Lardo	56245	1162

21874 7590 02/12/2007  
EDWARDS & ANGELL, LLP  
P.O. BOX 55874  
BOSTON, MA 02205

EXAMINER
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SHAY, DAVID M

ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/904,182	<b>Applicant(s)</b> LARDO ET AL.	
	<b>Examiner</b> david shay	<b>Art Unit</b> 3735	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on December 4, 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 61-67 and 69-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-67 and 69-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant argues that modifying Motamedi would render it “unsuitable for its intended purpose”. This argument is flawed in that Motamedi specifically teaches that the invention described therein drawn to “percutaneous treatment, with specific application to the ablation or modification tissues responsible for the arrhythmia...” As it has already been established that Motamedi teaches the superficial as well as the deep application of light for PDT (see the previous office action for a detailed discussion of this). It is also noted that a recognized treatment of arrhythmia is the ablation of the tissue which is causing the arrhythmia, such as the pulmonary vein, which would require superficial, annular light application.

Similarly, the fact that Swanson et al disclose the use of RF as the main embodiment does not remove therefrom the disclosure of the use of laser radiation and treatment of the pulmonary vein. Thus while applicant chooses to argue the RF embodiment, this is not the one used in the combination and as such these arguments are not convincing.

As applicant has relied upon the use of a balloon to enable the production of an annular pattern, the disclosure of Swanson et al, which employs a balloon in some embodiments, must similarly produce an annular pattern, else applicant’s disclosure is not enabling of this claim limitation.

Claims 61-63, 78-81, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motamedi in combination with Swanson and Altman. Motamedi teaches employing various methods, including photodynamic therapy to destroy tissue which causes arrhythmias. Swanson teaches that various means can be used to destroy tissue which causes arrhythmias; that

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determining the tissue to be ablated by stunning the tissue and seeing if the arrhythmia stops; and that various methods may be employed to locate the treatment device at the site. Swanson teaches, in addition to transmitting the energy, which can be laser light through a balloon, a guidance technique, which can include MRI; the energy application, which can include transmission of the tissue destroying energy through intervening media in contact with the tissue, to which the energy is essentially transparent; the application to atrial fibrillation; and incorporates by reference U.S. Patent No. 5,636,634, which discloses the infusion of saline or an anticoagulant. Altman teaches ablating to isolate the pulmonary vein to treat arrhythmia. It would have been obvious to the artisan of ordinary skill to employ the phototherapeutic treatment of Motamedi in the method of Swanson or to employ the guidance technique of Swanson, which can include MRI; the energy application, which can include transmission of the tissue destroying energy through intervening media in contact with the tissue, to which the energy is essentially transparent; and the application to atrial fibrillation in the method of Motamedi, and in either case to ablate the tissue which, when inhibited, stops the arrhythmia, such as the pulmonary vein, as taught by Altman, and to administer the photosensitizer via perfusing the coronary arteries, or by intravenous injection, since these are not critical; do not require site specific administration of the photosensitizer; and provide no unexpected result, and since Motamedi provides no particular delivery method, thus producing a method such as claimed.

Claims 64-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motamedi in combination with Swanson and Altman as applied to claims 61-63, 78-81, and 83 above, and further in combination with Leone. Leone teaches a porous balloon for delivering a

photodynamic therapy substance which is also injected with saline. It would have been obvious to the artisan of ordinary skill to use a porous balloon to deliver the photodynamic therapy substances in the method of Motamedi et al, since Motamedi et al provide no particular delivery method, and to insert the fiber into the balloon prior to the balloon being placed in the vein ostia, since this is not critical, would ensure that the fiber is properly located within the balloon, and provides no unexpected result; to apply a point or linear source of light, since these are well known irradiation patterns; would provide greater control over light application; and provides no unexpected result, thus producing a method such as claimed.

Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Motamedi in combination with Swanson and Altman as applied to claims 61-63, 78-81, and 83 above, and further in combination with Rice et al. Rice et al teach that phthalocyanines are appropriate photosensitizers. It would have been obvious to the artisan of ordinary skill to employ phthalocyanines as the photosensitizers, since these are effective as photosensitizers and Motamedi teaches no particular photosensitizer, thus producing a method such as claimed.

Applicant's arguments filed December 4, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

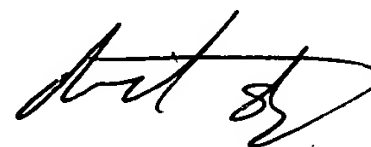
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY  
PRIMARY EXAMINER  
GROUP 330